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				Application Number	10/694,436
INFO	RMATION	DIÆCTÖ	SURE	Filing Date	October 27, 2003
STAT	EMENT B	Y APPEN	了研究	Confirmation Number	8942
				First Named Inventor	Kathleen C.M. Campbell
(use as	many she	ets as nec	cessary)	Group Art Unit	1614
				Examiner Name	Shirley V. Gembeh
Sheet	1	of	1	Attorney Docket No.	SIU 7397

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IPE	First Named Inventor	Kathleen C.M. Campbell	
O' 40 gg	Group Art Unit	1614	
DEC 07 2005 W	Examiner Name	Brian Yong S. Kwon	
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SG	29	wo	02/060491	A2	Diatide, Inc.	08-08-2002	
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	30	International Search Report for analogous application Serial No. PCT/US04/035626 dated September 8, 2005. NOT A PUBLISHED DOCUMENT					

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E JC 87 30	First Named Inventor	Campbell	
Q John M	Group Art Unit	not yet assigned	
	Examiner Name	not yet assigned	
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		OTHER ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T⁵
SG	1.	BENEVENGA, Norlin J., "Toxicities of Methionine and Other Amino Acids", <i>Journal of Agricultural and Food Chemistry</i> , January-February 1974, pages 2-9, Volume 22, Number 1, American Chemical Society, Easton, Pennsylvania	
SG	2.	BLOM, Henk J. et al., "Transamination of methionine in humans", <i>Clinical Science</i> , 1989, pages 43-49, Volume 76, Medical Research Society, London	
SG	3.	CAMPBELL, Kathleen C.M. et al., "p-Methionine protects against cisplatin damage to the stria vascularis", <i>Hearing Research</i> , 1999, pages 13-28, Volume 138, Elsevier Science, Amsterdam	
SG	4.	CAMPBELL, Kathleen C.M. et al., "p-Methionine provides excellent protection from cisplatin ototoxicity in the rat", <i>Hearing Research</i> , December 1996, pages 90-98, Volume 102, Number ½, Elseview Science, Amsterdam	
SG	5.	DONNELLY, J.P. et al., "Can anything be done about oral mucositis?", Annals of Oncology, 2003, pages 505-507, Volume 14, European Society for Medical Oncology	
SG	6.	FRIEDMAN, Mendel, "Chemistry, Nutrition, and Microbiology of D-Amino Acids", <i>Journal of Agricultural and Food Chemistry</i> , September 1999, pages 3457-3479, Volume 47, Number 9, The American Chemical Society, Easton, Pennsylvania	
SG	7.	GHIBELLI, L. et al., "Rescue of cells from apoptosis by inhibition of active GSH extrusion", Faseb Journal, April 1998, pages 479-486, Abstracts Part II, Volume 12, Number 5, Federation of American Societies for Experimental Biology, Bethesda, Maryland	
SG	8.	KAJI, Hiroshi et al., "Urinary 3-Methylthiopropionate Excretion and the Effect of D- or L-Methionine Ingestion Studied in Healthy Subjects", <i>Chemical Pathology and Pharmacology</i> , April 1987, pages 101-109, Volume 56, Number 1, P.J.D. Publications, Westbury, New York	
SG	9.	KIES, Constance et al., "Comparative Value of L-, DL-, and D-Methionine Supplementation of an Oat-based Diet for Humans", <i>The Journal of Nutrition</i> , July 1975, pages 809-814, Volume 105, Number 7, The American Institute of Nutrition, Bethesda, Maryland	

	Examiner Signature	/Shirley Gembeh/	Date Considered	04/11/2006
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O'M' PURY O'M' OUY	Group Art Unit	not yet assigned		
III SEE	Examiner Name	not yet assigned		
Sheetare 2 of 3	Attorney Docket No.	SIU 7397		

SG	10.	LU, S., "Regulation of Hepatic Glutathione Synthesis", <i>Seminars in Liver Disease</i> , 1998, pages 331-334, Volume 18, Number 4, Thieme Medical Publishers, Inc., New York
SG	11.	NATIONAL RESEARCH COUNCIL., Recommended Dietary Allowances, 1980, Ninth Edition, Washington D.C.
SG	12.	RESER, David et al., "L- and D-Methionine Provide Equivalent Long Term Protection Against CDDP-Induced Ototoxicity <i>In Vivo</i> , with Patrial <i>In Vitro</i> and <i>In Vivo</i> Retention of Antineoplastic Activity", <i>Neuro Toxicology</i> , October 1999, pages 731-748, Volume 20, Number 5, Intox Press, Inc., Redfield, Arkansas
. SG	13.	SONIS, S.T., "Mucositis as a biological process: a new hypothesis for the development of chemotherapy-induced stomatotoxicity", <i>Oral Oncology</i> , January 1998, pages 39-43, Volume 34, Number 1, Pergamon
· SG	14.	SONIS, Stephen T. et al., "Editorial - Prevention of mucositis in cancer patients", Journal of the National Cancer Institute - Mucosal Injury in Cancer Patients: New Strategies for Research and Treatment, 2001, pages 1-2, Number 29, U.S. Dept. of Health and Human Services, Washington D.C.
SG	15.	STEGINK, Lewis D. et al., "Effects of Equimolar Doses of L-Methionine, p-Methionine and L-Methionine-dl-Sulfoxide on Plasma and Urinary Amino Acid Levels in Normal Adult Humans", The Journal of Nutrition, July 1986, pages 1185-1192, Volume 116, Number 7, The Wistar Institute of Anatomy and Biology, Philadelphia, Pennsylvania
SG	16.	STEKOL, Jakob A. et al., "Pathological Effects of Excessive Methionine in the Diet of Growing Rats", The Journal of Nutrition, May 1962, pages 81-90, Volume 77, Number 1, The Wistar Institute of Anatomy and Biology, Philadelphia, Pennsylvania
SG	17.	WALSER, Mackenzie et al., "The Effect of Keto-analogues of Essential Amino Acids in Severe Chronic Uremia", <i>The Journal of Clinical Investigation</i> , January 1973, pages 678-690, Volume 52, Number 1, The American Society for Clinical Investigation, Inc., New York, New York
SG	18.	WHO EXPERT COMMITTEE, The Use of Essential Drugs: Eighth report of the WHO Expert Committee (including the revised Model List of Essential Drugs), December 1997, WHO Technical Report Series 882, World Health Organization, Geneva

Examiner Signature	/Shirley Gembeh/	Date Considered	04/11/2006

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Sheet	3	of PATENTS TRA	Attorney Docket No.	SIU 7397

SG	19.	WINGARD, John R., "Infectious and Noninfectious Systemic Consequences", National Cancer Institute Monographs - Consensus Development Conference on Oral Complications of Cancer Therapies: Diagnosis, Prevention, and Treatment, 1990, pages 21-26, Number 9, U.S. Department of Health and Human Services, Bethesda, Maryland	
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